

CLAIMS

What is claimed is:

1. A method of preparing an immunologically inert graft material comprising the steps of:
 - procuring body tissues from one of an autologous, heterologous or allogenic source;
 - soaking the body tissues in a bleach solution;
 - rinsing the body tissues in water to remove bleach solution from the tissues;
 - washing the body tissues in a detergent solution;
 - rinsing the body tissue to remove the detergent solution.
 - trimming the body tissue to a desired physical form;
 - soaking the body tissue in an iodophor solution;
 - rinsing the body tissue to remove the iodophor solution;
 - soaking the body tissue in a hypertonic solution;
 - rinsing the body tissue to remove the hypertonic solution therefrom;
 - agitating the body tissue in a caustic solution;

15 rinsing the body tissue in water under agitation to remove the caustic solution
16 therefrom;
17 treating the body tissue with a peroxide solution under agitation;
18 rinsing the body tissue in sterile water; and
19 conserving the body tissues in a sterile environment until needed.

2. The method of preparing a graft material of claim 1 wherein the hypertonic solution is a saline solution.

3. The method of preparing a graft material of claim 1 wherein the step of soaking the body tissue in a hypertonic solution further comprises the steps of:
soaking the body tissue in a series of increasingly hypertonic solutions and
rinsing the body tissue after each soaking in a hypotonic solution to remove the hypertonic solution therefrom.

4. The method of preparing a graft material of claim 1 wherein the caustic solution comprises one of sodium hydroxide, potassium hydroxide, ammonium hydroxide, calcium hydroxide, sodium dodecylsulfate, urea, phenol, and formic acid.

1 5. The method of preparing a graft material of claim 1 wherein the caustic solution
2 comprises a sodium hydroxide solution having a concentration of between .75 N
3 and 1.25N.

1 6. The method of preparing a graft of material of claim 3 wherein the series of
2 hypertonic solutions comprise 2%, 4%, 6%, 8%, 10% and 12% saline solutions.

1 7. The method of preparing a graft material of claim 1 wherein the body tissue is
2 immersed in hydrogen peroxide in a reaction chamber comprising:

3 a receptacle portion into which hydrogen peroxide and the body tissue are
4 placed;

5 an agitation that is supported upon an axle with in the receptacle and which
6 rotates so as to agitate the hydrogen peroxide and body tissue; and

7 a perforated cover placed over the receptacle so as to maintain the body tissue
8 below the surface of the hydrogen peroxide.

- 1 8. An immunologically inert graft material produced by the method of claim 1.
- 1 9. A method of preparing an immunologically inert graft material comprising the
2 steps of:
3 washing the body tissue in a detergent solution;
4 treating the body tissue with one or more anti-microbial and anti-viral solutions;
5 soaking the body tissue in a hypertonic solution;
6 soaking the body tissue in a solution comprising a caustic reagent;
7 treating the body tissue with a hydrogen peroxide solution; and
8 conserving the body tissue in a sterile environment.
- 9 10. A method of preparing an implantable graft material by removing cellular
10 components from a preexisting extra cellular matrix comprising the steps of:
11 freezing and subsequently thawing an untreated portion of the extracellular
12 matrix in a bleach solution;
13 washing the extracellular matrix in a detergent solution;
14 lysing cellular components present in the extracellular matrix by soaking the
15 extracellular matrix in a hypertonic solution;

8 soaking the extracellular matrix in a solution of sodium hydroxide; and,

9 soaking the extracellular matrix in a solution of hydrogen peroxide.

1 11. The method of preparing an implantable graft material of claim 10 further
2 comprising the step of treating the extracellular matrix with an antibacterial
3 agent.

5
1 12. The method of preparing an implantable graft material of claim 10 further
2 comprising the step of soaking the extra cellular material in an iodophor solution.

13. The method of preparing an implantable graft material of claim 10 further
2 comprising the step of treating the extracellular matrix with an antibiotic solution.

14. The method of preparing an implantable graft material of claim 10 further
2 comprising the step of treating the extracellular matrix with an antibiotic solution
3 comprising kanamycin.

1 15. The method of preparing a graft material of claim 1 wherein the body tissue is
2 additionally treated with a bactericidal agent.

1 16. The method of preparing a graft material of claim 1 wherein the hydrogen
2 peroxide solution may be replaced by one of peracetic acid, perbenzoic acid,
3 benzoyl peroxide, sodium peroxide, and potassium permanganate.

1 17. The method of preparing an immunologically inert graft material of claim 9
2 wherein the anti-bacterial solution comprises one of an iodophor and a bleach.

1 18. The method of preparing an immunologically inert graft material of claim 9
2 wherein the anti-bacterial solution comprises one of povidone-iodine, sodium
3 hypochlorite, and calcium hypochlorite.

1 19. The method of preparing an immunologically inert graft material of claim 10
2 wherein one of potassium hydroxide, ammonium hydroxide, calcium hydroxide,
3 sodium dodecylsulfate, urea, phenol, and formic acid may be substituted for
sodium hydroxide.

1 20. The method of preparing an immunologically inert graft material of claim 9
2 wherein one of peracetic acid benzoyl peroxide, sodium peroxide, potassium
3 permanganate may be substituted for hydrogen peroxide.

1 21. The method of preparing an immunologically inert graft material of claim 9
2 wherein the bleach solution may comprise one of sodium hypochlorite and
3 calcium hypochlorite.

1 22. The method of preparing an immunologically inert graft material of claim 10
2 wherein an iodophor may be substituted for the bleach solution.

1 23. The method of preparing an immunologically inert graft material of claim 22
2 wherein the iodophor comprises povidone-iodine.

1 24. The method of preparing an immunologically inert graft material of claim 1
2 further comprising the steps of initially freezing the body tissues in a first bleach
3 solution for a predetermined time and at a predetermined temperature and then
4 thawing the body tissues in a second bleach solution.

1 25. The method of preparing an immunologically inert graft material of claim 9
2 further comprising the step of freezing, and subsequently thawing a preselected
3 quantity of body tissue in a bleach solution.

1 26. A method of preparing an immunologically inert graft material from a body tissue
2 having cellular material disposed within an extracellular matrix comprising the
3 steps of:

4 lysing the cellular material disposed within the extracellular matrix by cycling the
5 relative osmotic pressure the cellular material is exposed to by
6 alternately exposing the body tissue to a hypertonic solution and a
7 hypotonic solution;

deactivating antigens present in the body tissue by exposing the body tissue to
at least one of a bleach solution, sodium hydroxide, and an iodophor
solution; and,
stabilizing the body tissue by soaking it in an isotonic solution.

27. The method of preparing an immunologically inert graft material from a body
tissue of claim 26 further comprising the step of exposing the body tissue to a
sodium hydroxide solution.

28. The method of preparing an immunologically inert graft material from a body
tissue of claim 26 further comprising the step of exposing the body tissue to a
hydrogen peroxide solution.

29. The method of preparing an immunologically inert graft material from a body
tissue of claim 26 further comprising the step of exposing the body tissue to an
antibiotic solution.

30. The method of preparing an immunologically inert graft material from a body
tissue of claim 26 further comprising the step of initially freezing the body tissue
in a bleach solution.

31. The method of preparing an immunologically inert graft material from a body
tissue of claim 26 wherein the hypertonic and hypotonic solutions are ionic and
non-ionic aqueous solutions, respectively.

1 32. The method of preparing an immunologically inert graft material from a body
2 tissue of claim 26 wherein the hypertonic solution is an aqueous saline solution
3 and the hypotonic solution is water.

1 33. The method of preparing an immunologically inert graft material from a body
2 tissue of claim 32 wherein the body tissue is exposed to an increasingly
3 hypertonic series of saline solutions.